

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 25 April 2001 (25.04.01)	
International application No. PCT/US00/17082	Applicant's or agent's file reference 1321.2.29
International filing date (day/month/year) 21 June 2000 (21.06.00)	Priority date (day/month/year) 21 June 1999 (21.06.99)
Applicant ADDERSON, Elisabeth et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 03 January 2001 (03.01.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Kiwa Mpay Telephone No.: (41-22) 338.83.38
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(19) World Intellectual Property Organization
International Bureau



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C07K 1/00, A61K 39/09, 39/38, 38/385, C12N 15/00,
15/09, C12P 21/04, G01N 33/53, 33/569

(74) Agent: MADSON & METCALF; 15 West South Temple,
Suite 900, Salt Lake City, UT 84101 (US).

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(71) Applicant (for all designated States except US): UNIVER-
SITY OF UTAH RESEARCH FOUNDATION [US/US];
Suite 110, 615 Arapen Drive, Salt Lake City, UT 84108
(US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): ADDERSON, Elis-
abeth [US/US]; St. Jude Children's Research Hospital,
Room D 2038, 332 N. Lauderdale, Memphis, TN 38105
(US). BOHNSACK, John [US/US]; University of Utah
Health Sciences Center, Dept. of Pediatrics, 50 North Med-
ical Drive, Salt Lake City, UT 84132 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ,
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LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ,
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patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
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CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

- With international search report.
- Before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments.

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: ISOLATED GENES FROM VIRULENT GROUP B <I>STREPTOCOCCUS AGALACTIAE</I>

(57) Abstract: The present invention relates to the identification and prevention of infections by virulent forms of Group B strepto-
cocci. Disclosed herein is the identification of two genes, *spb1* and *spb2*, that are specific to virulent type III-3 GBS. Also disclosed
herein are diagnostic methods for detecting virulent GBS infections and methods of immunizing a mammal against these bacteria.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/17082

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : Please See Extra Sheet.

US CL : Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 536/23.7; 530/350, 825; 424/244.1, 184.1, 236.1, 234.1, 193.1; 435/320.1, 69.3, 71.1, 7.1, 7.34

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DIALOG, MEDLINE, BIOSIS, EMBASE, WEST

spb1, spb2, GBS, SEQ ID NOs: 1, 2, 3 and 4, streptococc?, inventors' names

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P ----- Y,P	ADDERSON et al. Genetic subtraction identifies a novel respiratory epithelial adhesin/invasin of type III group B streptococcus (GBS). Pediatr. Res. 30 March 2000, Vol. 47, No. 4, page 337A, abstract 1992, see entire abstract.	1-16, 56 ----- 17-32, 33-55, 57-67

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*a* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

31 OCTOBER 2000

Date of mailing of the international search report

14 NOV 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

S. DEVI, Ph.D.

Telephone No. (703) 308-1235

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/17082

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☒ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/17082

A. CLASSIFICATION OF SUBJECT MATTER:

IPC (7):

C07H 21/04; C07K 1/00, A61K 39/09, 39/38, 39/39, 38/385; C12N 15/00, 15/09; C12P 21/04, G01N 33/53, 33/569

A. CLASSIFICATION OF SUBJECT MATTER:

US CL :

536/23.7; 530/350, 825; 424/244.1, 184.1, 236.1, 234.1, 193.1; 435/320.1, 69.3, 71.1, 7.1, 7.34

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

Group I, claim(s) 1-16, 33-35 and 56-60, drawn to an isolated nucleic acid molecule encoding SEQ ID NO: 2, a vector and a host cell comprising the same and a method of immunizing a mammal by administering a protein comprising SEQ ID NO: 2.

Group II, claim(s) 17-32, 38-40, 61-64 and 67, drawn to an isolated nucleic acid molecule encoding SEQ ID NO: 4, a vector and a host cell comprising the same and a method of immunizing a mammal by administering a protein comprising SEQ ID NO: 4.

Group III, claim(s) 42, 50 and 54, drawn to a diagnostic method comprising analyzing for the presence or absence of SEQ ID NO: 2.

Group IV, claims 43, 51 and 55, drawn to a diagnostic method comprising analyzing for the presence or absence of SEQ ID NO: 4.

Claims 36, 37, 65 and 66 are considered linking claims and would be joined with Group I or II, if elected.

Claims 41, 44-49, 52 and 53 are considered linking claims and would be joined with Group II or III, if elected.

The inventions listed as Groups I-IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I is directed to a nucleic acid molecule of SEQ ID NO:1, a protein with amino acid sequence of SEQ ID NO: 2, a vector and a host cell comprising the nucleic acid molecule and the first method of use of the protein in immunization. This is a permitted category under PCT Rule 13.2. Group II is directed to a second product, a nucleic acid molecule of SEQ ID NO:3, protein with amino acid sequence of SEQ ID NO: 4, a vector and a host cell comprising the nucleic acid molecule and a method of immunizing a mammal by administering the protein. Groups III and IV are directed respectively to a second method of use of the gene products, i.e., diagnostic methods for analyzing spb1 and spb2 gene products respectively. The SEQ ID NO.s of inventions I and II are the special technical features, which distinct from one another in their structure and specificity. The inventions therefore lack unity because the special technical feature is not a unifying feature.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14
REC'D 11 SEP 2001

WIPO

PCT

Applicant's or agent's file reference 1321.2.29	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/116)	
International application No. PCT/US00/17082	International filing date (day/month/year) 21 JUNE 2000	Priority date (day/month/year) 21 JUNE 1999
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant UNIVERSITY OF UTAH RESEARCH FOUNDATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 03 JANUARY 2001	Date of completion of this report 22 AUGUST 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer S. DEVI, Ph.D.
Facsimile No. (703) 305-3230	Telephone No. (703) 308-1235

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/17082

I. Basis of the report**1. With regard to the elements of the international application:***☒ the international application as originally filed☒ the description:pages 1-12 , as originally filedpages NONE , filed with the demandpages NONE , filed with the letter of _____☒ the claims:pages 13-16 , as originally filedpages NONE , as amended (together with any statement) under Article 19pages NONE , filed with the demandpages NONE , filed with the letter of _____☒ the drawings:pages 1-2 , as originally filedpages NONE , filed with the demandpages NONE , filed with the letter of _____☒ the sequence listing part of the description:pages 1-12 , as originally filedpages NONE , filed with the demandpages NONE , filed with the letter of _____**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**☒ contained in the international application in printed form.☒ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.**4. ☒ The amendments have resulted in the cancellation of:**☒ the description, pages NONE☒ the claims, Nos. NONE☒ the drawings, sheets/fig NONE**5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).****

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/17082

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☒ restricted the claims.
☐ paid additional fees.
☐ paid additional fees under protest.
☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
☒ not complied with for the following reasons:

Please See Supplemental Sheet.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report

- ☐ all parts.
☒ the parts relating to claims Nos. 1-16, 33-37, 56-60, 65 and 66.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/17082

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)

Claims 1-16, 33-37, 56-60, 65 and 66 YES

Claims NONE NO

Inventive Step (IS)

Claims 1-16, 33-37, 56-60, 65 and 66 YES

Claims NONE NO

Industrial Applicability (IA)

Claims 1-16, 33-37, 56-60, 65 and 66 YES

Claims NONE NO

2. citations and explanations (Rule 70.7)

Claims 1-16, 33-37, 56-60, 65 and 66 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the claimed nucleic acid molecules, vectors and host cells comprising the same, the protein and the method of using the same.

----- NEW CITATIONS -----
NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/17082

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 33 and 57 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims are indefinite for the following reason(s):

Claims 33 and 57 are incorrect in the recitation "streptococci infection" as opposed to —streptococcal infection—.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/17082

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): C07H 21/04; C07K 1/00, A61K 39/09, 39/38, 39/39, 38/385; C12N 15/00, 15/09; C12P 21/04, G01N 35/53, 33/569 and US Cl.: 536/23.7; 530/350, 825; 424/244.1, 184.1, 236.1, 234.1, 193.1; 435/320.1, 69.3, 71.1, 7.1, 7.34

IV. LACK OF UNITY OF INVENTION:

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2, and 13.3 is not complied with for the following reasons:

Group I, claim(s) 1-16, 33-35 and 56-60, drawn to an isolated nucleic acid molecule encoding SEQ ID NO: 2, a vector and a host cell comprising the same and a method of immunizing a mammal by administering a protein comprising SEQ ID NO: 2.

Group II, claim(s) 17-32, 38-40, 61-64 and 67, drawn to an isolated nucleic acid molecule encoding SEQ ID NO: 4, a vector and a host cell comprising the same and a method of immunizing a mammal by administering a protein comprising SEQ ID NO: 4.

Group III, claim(s) 42, 50 and 54, drawn to a diagnostic method comprising analyzing for the presence or absence of SEQ ID NO: 2.

Group IV, claims 43, 51 and 55, drawn to a diagnostic method comprising analyzing for the presence or absence of SEQ ID NO: 4.

Claims 36, 37, 65 and 66 are considered linking claims and would be joined with Group I or II, if elected.

Claims 41, 44-49, 52 and 53 are considered linking claims and would be joined with Group II or III, if elected.

The inventions listed as Groups I-IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I is directed to a nucleic acid molecule of SEQ ID NO:1, a protein with amino acid sequence of SEQ ID NO: 2, a vector and a host cell comprising the nucleic acid molecule and the first method of use of the protein in immunization. This is a permitted category under PCT Rule 13.2. Group II is directed to a second product, a nucleic acid molecule of SEQ ID NO:3, protein with amino acid sequence of SEQ ID NO: 4, a vector and a host cell comprising the nucleic acid molecule and a method of immunizing a mammal by administering the protein. Groups III and IV are directed respectively to a second method of use of the gene products, i.e., diagnostic methods for analyzing spb1 and spb2 gene products respectively. The SEQ ID NO.s of inventions I and II are the special technical features, which distinct from one another in their structure and specificity. The inventions therefore lack unity because the special technical feature is not a unifying feature.